IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEMS MDL NO. 2326
PRODUCTS LIABILITY LITIGATION

TO BE FILED IN LEAD CASE: 2:12-cv-08633

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

Civil Action Nos.	*Hendricks v. Boston Scientific Corp.*,	2:13-cv-03633;
	Moore v. Boston Scientific Corp.,	2:13-cv-08802;
	Tyree v. Boston Scientific Corp.,	2:13-cv-14397;
	Campbell v. Boston Scientific Corp.,	2:13-cv-18786;
	Blankenship v. Boston Scientific Corp.,	2:13-cv-22906;
	Pugh v. Boston Scientific Corp.,	2:14-cv-01565; and
	Wilson v. Boston Scientific Corp.,	2:14-cv-05475.

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF STEPHEN H. SPIEGELBERG, PH.D.

Pursuant to Federal Rules of Evidence 702, 403, and 104 Plaintiffs submit this Memorandum of Law in Support of Their Motion to Exclude the Opinions and Testimony of Stephen H. Spiegelberg, Ph.D.

Introduction and Summary

Dr. Spiegelberg is a chemical engineer who has experience in private laboratory polymer characterization and testing. Unfortunately, Dr. Spiegelberg attempts to opine on subjects well outside his expertise that are both unreliable and irrelevant. Specifically, Dr. Spiegelberg attempts to offer unreliable and inappropriate opinions about a corporation's state of mind and intent based on falsely cited deposition testimony. These opinions should be excluded by the Court.

Arguments and Authorities

The proponent of expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed.R.Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

Even if the expert is qualified and the testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Liti*g., 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must "fit" the case, *i.e.* there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id*.

A. Dr. Spiegelberg's Opinions Regarding Position Statements By Medical Organizations Should Be Struck.

Dr. Spiegelberg, a chemical engineer and owner of a polymer testing laboratory, attempts to offer expert opinions about a position statement offered by medical organizations. This chemist's characterization and use of medical society position statements should be excluded because: (1) he is unqualified to offer testimony on the topic, and (2) it lacks any reliable methodology.

In Dr. Spiegelberg's June 2, 2014 supplemental report he seeks to offer new opinions about the validity of position statements issued by the American Urogynecological Society

(AUGS) and Society for Female Urology and Urodynamics (SUFU). Exhibit A at pgs. 3-4 (Supplemental Report of Dr. Steven Spiegelberg); Exhibit B (January 2014 Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence). He opines about these organizations' state of mind and suggests that they have determined that all polypropylene is safe for use in all surgical implants. Exhibit A at pgs. 3-4.

Dr. Spiegelberg is a chemical engineer who has no "knowledge, skill, experience, training, or education" pertaining to urology, gynecology, and urogynecology. Fed.R.Evid. 702. Far from being a physician, Dr. Spiegelberg is not even a biomedical engineer. Similarly, he is not a member of AUGS or SUFU; has never treated anyone for a pelvic floor disorder; has never implanted mesh in a human being; and has absolutely no understanding of what AUGS of SUFU considered in crafting these statements. *See* Exhibit C (CV of Stephen Spiegelberg, Ph.D). Dr. Spiegelberg is not qualified to offer opinions regarding AUGS or SUFU position statements and any opinions referencing these statements should be excluded.

Not only is Dr. Spiegelberg not qualified to offer opinions pertaining to the AUGS of SUFU statements, his report is wholly devoid of any explanation as to the methodology utilized by these two organizations in forming these statements. Dr. Spiegelberg cannot identify why he relies on this document, how it is a document a chemical engineer would normally rely upon, or how the hearsay statements within it are reliable. Because he is neither a physician nor a member of AUGS or SUFU, he has absolutely no knowledge about why these organizations made these statements, what evidence they relied upon, of what they constitute. He offers no explanation or accepted chemical engineering standard on that point.

At the least, reliance on a statement of position by a private medical society should be subjected to the same rigor of scientific reliability that would apply to other material. The

January 2014 AUGS-SUFU Position Statement ("Statement") referenced in Dr. Spiegelberg's supplemental report was crafted by key opinion leaders for the mesh industry to vindicate the conduct of mesh manufacturers (including BSC) and to defend manufacturers and physicians in product liability actions. (Exhibit D). The mere fact that five industry-influenced and paid key opinion leaders drafted the Statement does not mean that the views expressed therein are the only valid, admissible opinions on the subject of the safety and efficacy of polypropylene slings.

The Statement was authored by the following five individuals – Drs. Charles Nager, Paul Tulikangas, Dennis Miller, Eric Rovner and Howard Goldman. (Exhibit B at pg. 3; Dr. Nager is President of AUGS. Exhibit E at 33:1-19; Exhibit F at 365:6-16). The Statement was adopted by the boards of directors of AUGS and SUFU. (Exhibit F at 516:3-520:15). The Statement was not presented to either societies' members for adoption nor does it reflect a survey of the organizations' members. (*Id*.). Further, the authors of the Statement all are or have been closely associated with mesh manufacturers. The authors' conflicts of interest with industry were not disclosed in the initial statement. (Exhibit E at pp. 273-274). Dr. Nager was a former paid speaker and preceptor for Ethicon. (*Id*. at 143-144; 318-319). Dr. Rovner is a consultant for American Medical Systems (AMS) (Exhibit G). Dr. Goldman is a key opinion leader for AMS and also served as a consultant for Ethicon from 2005 to 2011. (Exhibit H, (Doc. 119, pg. 2) 2:12-cv-05762, *Sanchez, et al. v. BSC*, "AMS has agreed to stipulate that 'Dr. Goldman is a Key Opinion Leader for AMS.'"). Dr. Tulikangas was a consultant for Ethicon. (Exhibit I). Dr. Miller is a collaborator, consultant, and key opinion leader for BSC.

In fact, Dr. Miller's alliance with BSC goes well beyond that of a key opinion leader. Dr. Miller has a financial interest in certain BSC products. Dr. Miller is the inventor of the BSC Pinnacle product and co-inventor of the BSC Uphold product and receives royalties from BSC

for both products. (Exhibit F at 287:17 – 288:19; 328:16 – 328:23). In addition to these royalties, BSC has paid Dr. Miller for service as a consultant and for training of other doctors. (*Id.* at 288:13-19; 545:6 – 546:2). Dr. Miller also appeared at BSC's national sales meeting in 2008 to address BSC sales people. (*Id.* at 561:1-11).

Dr. Miller testified that the goals of the AUGS-SUFU MUS Task Force (which was responsible for the Statement) per Dr. Nager were "to prepare materials (e.g., a tool kit) for our members to help them with the unbalanced anti-MUS message confronting them daily from the media" and to "develop a position statement, frequently asked questions, and/or talking points" and the plan was to finish the task of drafting the statement in four to six weeks. (*Id*. at 349:22 – 351:2; 351:3 – 352:4; Exhibit J). The Statement was essentially created for use in defending lawsuits and to create a statement that "will get seen" and to create materials to "help our members deal with the onslaught and negativity." (Exhibit D; Exhibit F at 352:24 – 354:16; 374:13 – 375:4; 380:3 – 381:5; Exhibit J). Thus, the Statement was created to provide resources in dealing with "patients, media and lawyers/lawsuits" and to defend the use of midurethral slings. (Exhibit F at 387:9 – 388:7).

Further, the opinions contained in the Statement are also not properly supported. As Dr. Miller admitted under oath, the Statement is not an analysis of the literature on slings. (*Id.* at 539: 10-1). It is not a Cochrane analysis. (*Id.*)[1]. It is not a report of a randomized clinical trial (*Id.*). It is not peer-reviewed (Id.). It does not reflect a scientific analysis of the published literature. (*Id.* at 540:7-13). The Statement neglects to take into account the differences between retropubic and

[1] The Statement relies on Ogah Cochrane review. Dr. Blaivas testified that the Ogah review was flawed because the authors admitted that the quality of the evidence was only moderate, which in his view means "not very high quality" and the duration was not very long. **Exhibit K** at 263-267. Dr. Blaivas also testified that the authors of the 2011 Cochrane review cautioned that the conclusion that "traditional slings seem to be as effective as minimally invasive slings, but had higher rates of adverse effects," should be interpreted with some caution because the quality of evidence for the studies involving synthetic slings was variable, follow-up short and populations small. Id. at 269-275.

obturator slings, the difference in the reports results from clinical trials on individual products, or the difference in the occurrence rates for adverse events. (*Id.* at 524:4-527:6, 539:24-542:24).

In some instances, individual authors of the Statement lack expertise with the products or the subject matter covered by the Statement. For example, Dr. Miller testified that though the opinions in the Statement apply to transobturator slings, he does not use nor has he ever utilized transobturator slings (like the Obtryx) (*Id.* at 536:15-21, 537:16-538:15). Dr. Miller's personal experience with midurethral slings is limited to BSC's Advantage and Ethicon's TVT, both of which use retropubic approaches (*Id.* at 536:1-3). Dr. Miller is not aware of the occurrence rates of adverse outcomes in transobturator products, including dyspareunia, pelvic pain, erosion, voiding dysfunction (*Id*. at 530:8-533:9).

In other instances, the authors wrote an assertion in the Statement without having any data or publication to support the conclusion. For example, the assertion that over 3 million midurethral slings have been placed worldwide and these procedures are used by greater than 99 percent of AUGS members was included in the statement prior to locating scientific support (Exhibit E at 262:21-265:15).

When considering Dr. Spiegelberg's complete lack of experience, education or background in relation to female pelvic mesh surgery, the flawed methodology by which the Statement was created, and the fact that Dr. Spiegelberg's methodology consisted of merely obtaining a copy of the Statement from defense counsel, which he cut and pasted into his report, his opinions on this matter fail to meet the requirements of *Daubert* and should therefore be excluded.

Further, the AUGS and SUFU position statement is not a good fit for this case because there is not "a valid scientific connection to the pertinent inquiry." *In re Ethicon, Inc., Pelvic*

Repair Sys. Products Liab. Litig., 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). For all of the foregoing reasons, Dr. Spiegelberg's opinions should be excluded.

B. Dr. Spiegelberg's State Of Mind Or Intent Opinions Related To Material Safety Data Sheets (MSDS) Should Be Struck.

Dr. Speigelberg offers unreliable and unhelpful opinions related to material safety data sheets (MSDS) created by Chevron Phillips for the type of polypropylene used by Boston Scientific in its manufacturing of transvaginal mesh.[2] These MSDS opinions are a backdoor attempt by Dr. Spiegelberg to offer opinions about Chevron Phillips' state of mind or intent which has routinely been excluded by this Court. *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013). These same opinions should be excluded here.

At issue are the MSDS created by Chevron Phillips, the manufacturer of the Marlex polypropylene used in Boston Scientific mesh products, including the Obtryx product. Chevron Phillips added the following statement in the Marlex MSDS:

> MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Exhibit L at pg. 1. Lacking any personal knowledge or identifying any review of relevant documents, Dr. Spiegelberg opines "[t]here is no evidence that Phillips Sumika Polypropylene Company or Chevron Phillips Chemical Company had a scientific basis for the inclusion of the

[2] Additionally, Dr. Spiegelberg has offered no evidence in his reports, deposition, or resume that he has any experience creating, reviewing, or analyzing MSDS. Therefore, he is likewise unqualified to offer opinions related to MSDS.

Medical Application Caution in the MSDS for Phillips Sumika Marlex HGX-030-01." Exhibit M at pg. 40 (Expert Report of Stephen Spiegelberg, Ph.D); Exhibit A at pg. 1 (Supplemental). Dr. Spiegelberg further offers the conclusion that Chevron Phillips included the Caution in the MSDS for "liability" concerns. Exhibit M at pg. 40. Dr. Spiegelberg's new basis for this opinion is his own version of a deposition of a Chevron Phillips employee, Mr. Frank Zakrzewski. Dr. Spiegelberg's supplemental report restating his version of testimony rather than quoting from the transcript citations:

- Indeed, Mr. Zakrzewski testified that the statement *was not* added based on scientific testing, data, or literature on polypropylene - and that the statement is not unique to polypropylene MSDSs. (54:19-55:1).

- During his corporate representative deposition, Mr. Zakrzewski testified that the medical application statement was not added based on: scientific testing (45:24-46:5, 64:22-65:4,66:8-13, 183:9-14); scientific data (46:6-11); any scientific basis (184:11-14); review of any scientific or medical literature (47:8-15); or scientific concerns with vaginal mesh (47:16-21)….

- Mr. Zakrzewski explicitly testified that there was no scientific basis, data, or testing of the polypropylene when revising the MSDS in 2004, and that CP Chern did not add the statement based on any scientific or medical concerns with transvaginal mesh.

Exhibit A at pgs. 2-3. While this entire effort is an inappropriate attempt by Dr. Spiegelberg to testify as to Chevron Phillips' state of mind, the most fatal flaw in this effort is exposed when one looks at the actual testimony. When one looks at Mr. Zakrzewski's actual deposition, it does not say what Dr. Spiegelberg claims it says. Instead, Mr. Zakrzewski specifically and repeatedly testified that he is "not aware" and does not know one way or the other if there was a scientific basis for the addition of the Medical Application Caution and that any opinion he could offer would be pure "speculation." Plaintiff apologizes for the length of the following deposition quotes but they are necessary for the Court to see the methodological flaws and inaccuracies in Mr. Spiegelberg's opinions:

Deposition of Frank Zakrzewski

Q. There's no scientific basis for the statement in the MSDS?

A. That would be speculation. I don't know.

Q. You're not aware of any --

A. I'm not aware of any.

Q. -- scientific basis to support the MSDS --

Q. -- medical caution statement?

A. Yeah, I wasn't involved in the change or what was added

Exhibit N at 183:16-184:8 (Deposition of Frank Zakrzewski);

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Q. Do you know who wrote the MSDS?

A. **I do not**.

Q. Was the medical application statement that we've highlighted in Deposition Exhibit 3 added to the polypropylene MSDS based on any scientific testing that was conducted?

A. **Not that I'm aware of, no**.

Q. And was the medical application statement for polypropylene in the MSDS marked as Deposition Exhibit 3 added based on any specific scientific data on polypropylene?

A. **No. Not that I'm aware of.**

Id. at 45:22-46:11;

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Q. Was the medical application statement that we're looking at in Deposition Exhibit 3 added to the polypropylene MSDS based on any review of the scientific or medical literature on polypropylene?

A. **Yeah, I'm not aware of any testing or information on polypropylene related to this statement.**

Id. at 47:8-47:15;

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Q. The fact that you do not know whether there is any specific testing does not mean that those statements don't have a scientific basis?

.

A. **I don't know the reasons that the statements were put on there.**

Id. at 140:16-23 (emphasis added). In fact, Mr. Zakrzewski explicitly removed any evidentiary basis for Dr. Spiegelberg's original speculative opinion that the MSDS language was added for liability lawsuits:

Q. Okay. Was the medical application statement added to the material safety data sheet for Marlex polypropylene in January of 2004 for legal reasons?

A. I would say that legal had some input into the MSDS, but I don't know that for certain because I didn't write it.

Id. at 45:13-20.

Dr. Spiegelberg cannot re-craft testimony and speculate as to a third party's state of mind in a desperate effort to justify his previous speculation that Chevron Phillips had no basis for the addition of the Medical Caution Application in the MSDS. Dr. Spiegelberg is burdened by the fact that this is not what Mr. Zakrzewski stated. Mr. Zakrzewski did "not know one way or another" why Chevron Phillips included the Medical Caution Application in the MSDS. There is no evidence to support any of Dr. Spiegelberg's speculations related to Chevron Phillips' reasoning for the MSDS language and his opinions are inherently flawed.

Dr. Spiegelberg's opinions about the MSDS are actually a backdoor attempt to testify as to Chevron Phillips' state or mind or intent. Absent the misquoted testimony of Mr. Zakrzewski, Dr. Spiegelberg has no evidence as to why Chevron Phillips included the Medical Application Caution in the MSDS, but somehow he opines that whatever the reason, it had no basis. This opinion is an attempt to opine on Chevron Phillips' state of mind. This Court has consistently held that such state of mind opinion—even when supported by evidence—"is not a proper subject for expert or even lay testimony." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab.*

Litig., 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013). For these reasons Dr. Spiegelberg's opinions related to MSDS should be excluded.

Conclusion

For the forgoing reasons, Dr. Spiegelberg's proposed testimony and opinions outlined above are inadmissible and should be excluded.

DATED: August 1, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2014, I electronically filed the foregoing Memorandum to Motion to Exclude with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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